510(k) Summary for exsalt™ T7 Wound Dressing

1. Trade (Proprietary) Name

exsalt™ T7 Wound Dressing

2. Common Name

Wound or Burn Dressing

3. Contact Information

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Canada

4. Device Classification & Panel

A final classification for wound/burn dressings has not been implemented; Class II has been proposed by the General & Plastic Surgery Devices Panel.

5. Predicate Device(s)

exsalt™ SD7 Wound Dressing (K103067)
exsalt™ SD7 Wound Dressing (K083870)

6. Device Description

Exciton Technologies Inc. has developed the exsalt™ technology, a proprietary chemical process, which deposits oxidized silver species onto a non-woven polyester with gray Delnet® HDPE mesh layers thermally bonded on both sides. Silver in the exsalt™ T7 Wound Dressing inhibits bacterial growth in the dressing. The concentration of the silver and oxidized silver

species on the dressing is 0.4 mg/cm^2 (4.5% w/w). The exsalt™ T7 Wound Dressing is known to be effective *in vitro* against *Staphylococcus aureus, Enterococcus faecalis, Staphylococcus epidermidis, Pseudomonas aeruginosa, and Acinetobacter baumannii for up to 7 days.*

7. Intended Use

exsalt™ T7 Wound Dressing is indicated for the management of partial and full thickness wounds, including decubitus ulcers, venous stasis ulcers, diabetic ulcers, first and second degree burns, grafts and donor sites, or other acute or chronic wounds. The dressing may be used over debrided and grafted wounds.

8. Summary of Substantial Equivalence

The labeled indications and directions for use of the exsalt™ T7 Wound Dressing are equivalent to those of the predicate device, exsalt™ SD7 Wound Dressing (K103067). The design, materials, and manufacturing process are the equivalent to those of the predicate device, exsalt™ SD7 Wound Dressing (K103067), and therefore do not raise any new issues concerning safety or effectiveness.

a) Summary of Technological Characteristics

The exsalt™ T7 Wound Dressing consists of 2 outer layers of HDPE with an inner layer of polyester which are all silver-coated. The skin-contacting materials in both the exsalt™ T7 Wound Dressing and the predicate are the same.

The exsalt™ T7 Wound Dressing is sterilized by gamma irradiation.

The change in the exsalt™ T7 Wound Dressing substrate configuration does not raise any concerns related to safety or effectiveness as compared to the predicate device (K103067).

b) Summary of Performance Data

The following performance tests were conducted on the exsalt™ SD7 Wound Dressing:

- Silver Content
- Moisture Content
- pH
- Absorbency
- Anti-bacterial Effectiveness; against *Staphylococcus aureus, Enterococcus faecalis, Staphylococcus epidermidis, Pseudomonas aeruginosa, and Acinetobacter baumannii*
- Bactericidal Effectiveness

- Biocompatibility
- Biological Reactivity

All performance characteristics of the exsalt™ T7 Wound Dressing are the same as the predicate(s).

The exsalt™ T7 Wound Dressing raised no new safety concerns relative to biocompatibility. Testing performed on the exsalt™ SD7 Wound Dressing (K083870) showed that it was non-toxic, non-irritant, and did not elicit a sensitization response.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 15 2011

Exciton Technologies, Inc.
% Ms. Melanie Ussyk
10230 Jasper Avenue, Suite 4000
Edmonton, Canada T5J 4P6

Re: K113564
Trade/Device Name:
Regulatory Class: Unclassified
Product Code: FRO
Dated: December 02, 2011
Received: December 02, 2011

Dear Ms. Ussyk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to
http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address
http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

exsalt™ T7 Wound Dressing Indications for Use

510(k) Number: ~~K103067~~ K113564

Device Name: exsalt™ T7 Wound Dressing

Indications for Use:

The exsalt™ T7 Wound Dressing is indicated for use in partial and full thickness wounds, including decubitus ulcers, venous stasis ulcers, diabetic ulcers, first and second degree burns, grafts and donor sites, or other acute or chronic wounds. The dressing may be used over debrided and grafted wounds. The exsalt™ T7 Wound Dressing provides an antibacterial barrier that inhibits bacterial growth in the dressing for up to 7 days.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use _____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113564